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09/932,512	08/17/2001	Thomas E. Borillo	593/004	6335

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,512

Applicant(s)

BORILLO ET AL.

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. In response to applicant's amendment of 12/24/2003, the examiner has removed all prior *35 USC § 112* rejections.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 and 18-20 are rejected under 35 U.S.C. 102 (e) as being anticipated by Lesh et al. (U.S. 6,152,144).

Note in figs. 6-7, 9, col. 1, lines 64-67 and col. 2, lines 1-67, a device having all the limitations of claim 1, including: a tube (72) has a first closed end that comprises a blood filter (63); an expandable structure (65) has a collapsed configuration and an expanded configuration; and wherein the device is inserted in the appendage while the expandable structure (65) is in the collapsed configuration. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Lesh et al reference which is capable of being used as claimed if one desires to do so.

Regarding claims 2-4, wherein the tube (72) has a cylindrical shape; and wherein the tube comprises a blood filter (63).

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Regarding claims 5-6, wherein the expandable structure (65) is self-expanding; and wherein the expandable structure expands from the collapsed configuration to the expanded configuration by an inflatable balloon (labeled in col. 9, lines 29-41).

Regarding claims 7-9, wherein the device further comprises a self-sealing opening (labeled in col. 10, lines 3-9) for withdrawing the inflatable balloon.

Regarding claims 10-12 and 19, wherein the tube comprises elastomeric material, braided material and woven material (col. 2, lines 30-67 and col. 3, lines 1-9); and wherein the filter (63) comprises holes to harmful-size emboli. Regarding claim 18, wherein a filter element (63) has a predetermined size; item 72 can be characterized as an elastic or biocompatible tube that is attached to the filter element; an expandable structure (65) is for deploying the cover. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Lesh et al reference which is capable of being used as claimed if one desires to do so.

Regarding claim 20, the filter element is made of material that is less elastic than the expandable membrane (inherent feature, item 63 is made from polyurethanes, polyethylene, labeled in col. 2, lines 36-45, col. 3, lines 4-10 and col. 9, lines 51-57).

Response to Arguments

3. Applicant's arguments filed 12/24/2003 have been fully considered but they are not persuasive. With respect to claim 1, In response to applicant's argument that the reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., continuous open channels through the porous membrane of the biomaterials and

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further suggest techniques for drilling such open channels) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner disagrees with Applicant's remarks that the filter of Lesh can neither teach nor suggest a filter feature for allowing the passage of fluids, blood or gases. As the examiner has pointed out above, item 61, 63, figs 6-7 of Lesh can be characterized as a mesh or a filter. In any event, Lesh discloses that item 61, 63 is a mesh. By definition, i.e., a mesh is defined as something that snares or entraps (inherent feature, item 61, 63 can block tissue but permit fluid flows.). Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Lesh et al reference which is capable of being used as claimed if one desires to do so. Therefore, at least claim 1 of the invention is not defined over the Lesh et al'144 reference.

Conclusion

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn Vn
March 5, 2004


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